under a claim of tariff item 851.60, the applicant (directly or through his/her agent) shall at the earliest possible date supply the stamped copy to the Port. Further instructions for entering instruments are contained in §301.8 of the regulations.

[47 FR 32517, July 28, 1982; 47 FR 34368, Aug. 9, 1982, as amended at 50 FR 11501, Mar. 22, 1985]

§ 301.5 Processing of applications by the Department of Commerce.

(a) *Public notice and opportunity to present views.* (1) Within 10 days of receipt of an application from the Commissioner, the Director shall make a copy available for public inspection during ordinary business hours of the Department of Commerce. Unless the Director determines that an application has deficiencies which preclude consideration on its merits (e.g., insufficient description of intended purposes to rule on the scientific equivalency of the foreign instrument and potential domestic equivalents), he shall publish in the FEDERAL REGISTER a notice of the receipt of the application to afford all interested persons a reasonable opportunity to present their views with respect to the question ''whether an instrument or apparatus of equivalent scientific value for the purpose for which the article is intended to be used is being manufactured in the United States.'' The notice will include the application number, the name and address of the applicant, a description of the instrument(s) for which duty-free entry is requested, the name of the foreign manufacturer and a brief summary of the applicant's intended purposes extracted from the applicant's answer to question 7 of the application. In addition, the notice shall specify the date the application was accepted by the Commissioner for transmittal to the Department of Commerce.

(2) If the Director determines that an application is incomplete or is otherwise deficient, he may request the applicant to supplement the application, as appropriate, prior to publishing the notice of application in the FEDERAL REGISTER. Supplemental information/material requested under this provision shall be supplied to the Director in two copies within 20 days of the date of the request and shall be subject to the certification contained in Question 11 of the form. Failure to provide the requested information on time shall result in a denial of the application without prejudice to resubmission.

(3) *Requirement for presentation of views (comments) by interested persons.* Any interested person or government agency may make written comments to the Director with respect to the question whether an instrument of equivalent scientific value, for the purposes for which the foreign instrument is intended to be used, is being manufactured in the United States. Except for comments specified in paragraph (a)(4) of this section, comments should be in the form of supplementary answers to the applicable questions on the application form. Comments must be postmarked no later than 20 days from the date on which the notice of application is published in the FEDERAL REGISTER. In order to be considered, comments and related attachments must be submitted to the Director in duplicate; shall state the name, affiliation and address of the person submitting the comment; and shall specify the application to which the comment applies. In order to preserve the right to appeal the Director's decision on a particular application pursuant to §301.6 of these regulations, a domestic manufacturer or other interested person must make timely comments on the application. Separate comments should be supplied on each application in which a person has an interest. However, brochures, pamphlets, printed specifications and the like, included with previous comments, if properly identified, may be incorporated by reference in subsequent comments. If the Director knows of the availability of a domestic instrument which may be comparable to the foreign instrument, he may: (i) Require the applicant to compare the domestic instrument with the foreign instrument; or (ii) compare the two instruments whether or not comments are received from a domestic manufacturer on the specific application.

(4) *Comments by domestic manufacturers.* Comments of domestic manufacturers opposing the granting of an application should:

(i) Specify the domestic instrument considered to be scientifically equivalent to the foreign article for the applicant's specific intended purposes and include documentation of the domestic instrument's guaranteed specifications and date of availability.

(ii) Show that the specifications claimed by the applicant in response to question 8 to be pertinent to the intended purpose can be equaled or exceeded by those of the listed domestic instrument(s) whether or not it has the same design as the foreign instrument; that the applicant's alleged pertinent specifications should not be considered pertinent within the meaning of § 301.2(s) of the regulations for the intended purposes of the instrument described in response to question 7 of the application; or that the intended purposes for which the instrument is to be used do not qualify the instrument for duty-free consideration under the Act.

(iii) Where the comments regarding paragraphs (a)(4)(i) and (a)(4)(ii) of this section relate to a particular accessory or optional device offered by a domestic manufacturer, cite the type, model or other catalog designation of the accessory device and include the specification therefor in the comments.

(iv) Where the justification for duty-free entry is based on excessive delivery time, show whether:

(A) The domestic instrument is as a general rule either produced for stock, produced on order, or custom-made and;

(B) An instrument or apparatus of equivalent scientific value to the article, for the purposes described in response to question 7, could have been produced and delivered to the applicant within a reasonable time following the receipt of the order.

(v) Indicate whether the applicant afforded the domestic manufacturer an opportunity to furnish an instrument or apparatus of equivalent scientific value to the article for the purposes described in response to question 7 and, if such be the case, whether the applicant submitted a formal invitation to bid that included the technical requirements of the applicant.

(5) *Untimely comments.* Comments must be made on a timely basis to ensure their consideration by the Director and the technical consultants, and to preserve the commenting person's right to appeal the Director's decision on an application. The Director, in his discretion, may entertain comments filed untimely to the extent that they contain factual information, as opposed to arguments, explanations or recommendations.

(6) *Provision of general comments.* A domestic manufacturer who does not wish to oppose duty-free entry of a particular application, but who desires to apprise the Director of the availability and capabilities of its instrument(s), may at any time supply documentation to the Director without reference to a particular application. Such documentation shall be routinely taken into account by the Director when applications involving comparable foreign instruments are received. The provision of general comments does not preserve the commentor's right to appeal the Director's decision on a particular application.

(7) *Provision of application to domestic manufacturers.* To facilitate timely comments, the Director may furnish copies of certain applications to domestic manufacturers who intend to comment on applications, provided:

(i) The manufacturer requests the service in writing;

(ii) The manufacturer provides copies of current company literature regarding the domestic instrument and its guaranteed capabilities; and

(iii) The manufacturer identifies the specific models or types of comparable foreign instrument(s) that it proposes to comment on. The Director may furnish for comment copies of the appropriate applications to the domestic manufacturer until the firm requests that the service be discontinued, provided the firm utilizes the service to supply written comments on applications. If the recipient of the service fails to avail itself of the opportunity to comment on appropriate applications for a period of one year, the Director may at his discretion discontinue the service. For reasons of cost and administrative burden, the service may be discontinued at the discretion of the Director. In such case the Director shall notify all recipients

of the service in writing of such discontinuance.

(b) *Additions to the record.* The Director may solicit from the applicant or from foreign or domestic manufacturers, and agents thereof, or any other person or Government agency considered by the Director to have competence on any issue pertaining to an application, any additional information the Director deems necessary to the rendering of a decision. The Director may attach such conditions and time limitations deemed appropriate upon the provision of such information and may draw appropriate inferences from a person's failure to provide the requested information.

(c) *Advice from technical consultants.*

(1) The Director shall consider any written advice from the Secretary of HHS, or his delegate, on the question whether a domestic instrument of equivalent scientific value to the foreign instrument, for the purposes for which the instrument is intended to be used, is being manufactured in the United States.

(2) After the comment period has ended (§ 301.5(a)(3)), the complete application and any comments received and related information are forwarded to the appropriate technical consultants for their written advice.

(3) The technical consultants are requested to provide their written recommendation within 30 days of the date of transmittal. The technical consultants relied upon for advice may include, but are not limited to, the National Institutes of Health (delegated the function by the Secretary of HHS), the National Bureau of Standards and the National Oceanographic and Atmospheric Administration.

(d) *Criteria for the determinations of the Department of Commerce*—(1) *Scientific equivalency.* (i) The determination of scientific equivalency shall be based on a comparison of the pertinent specifications of the foreign instrument with similar pertinent specifications of comparable domestic instruments (see § 301.2(s) for the definition of pertinent specification). Ordinarily, the Director will consider only those performance characteristics which are ''guaranteed specifications'' within the meaning of § 301.2(r) of this part. In no event, however, shall the Director consider performance capabilities superior to the manufacturer's guaranteed specifications or their equivalent. In making the comparison the Director may consider a reasonable combination of domestic instruments that combines two or more functions into an integrated unit if the combination of domestic instruments is capable of accomplishing the purposes for which the foreign instrument is intended to be used. If the Director finds that a domestic instrument possesses all of the pertinent specifications of the foreign instrument, he shall find that there is being manufactured in the United States an instrument of equivalent scientific value for such purposes as the foreign instrument is intended to be used. If the Director finds that the foreign instrument possesses one or more pertinent specifications not possessed by the comparable domestic instrument(s), the Director shall find that there is not being manufactured in the United States an instrument of equivalent scientific value to the foreign instrument for such purposes as the foreign instrument is intended to be used.

(ii) Programs that may be undertaken at some unspecified future date shall not be considered in the Director's comparison. In making the comparison, the Director shall consider only the instrument and accompanying accessories described in the application and determined eligible by the U.S. Customs Service. The Director shall not consider the planned purchase of additional accessories or the planned conversion of the article at some unspecified future time for such programs.

(iii) In order for the Director to make a determination with respect to the ''scientific equivalency'' of the foreign and domestic instruments, the applicant's intended purposes must include either scientific research or science-related educational programs. Instruments used exclusively for nonscientific purposes have no scientific value, thereby precluding the requisite finding by the Director with respect to ''whether an instrument or apparatus of equivalent scientific value to such article, for the purposes for which the article is intended to be used, is being

manufactured in the United States.'' In such cases the Director shall deny the application for the reason that the instrument has no scientific value for the purposes for which it is intended to be used. Examples of nonscientific purposes would be the use of an instrument in routine diagnosis or patient care and therapy (as opposed to clinical research); in teaching a nonscientific trade (e.g., printing, shoemaking, metalworking or other types of vocational training); in teaching nonscientific courses (e.g., music, home economics, journalism, drama); in presenting a variety of subjects or merely for presenting coursework, whether or not science related (e.g., video tape editors, tape recorders, projectors); and in conveying cultural information to the public (e.g., a planetarium in the Smithsonian Institution).

(2) *Manufactured in the United States.* An instrument shall be considered as being manufactured in the United States if it is customarily ''produced for stock,'' ''produced on order'' or ''custom-made'' within the United States. In determining whether a U.S. manufacturer is able and willing to produce an instrument, and have it available without unreasonable delay, the normal commercial practices applicable to the production and delivery of instruments of the same general category shall be taken into account, as well as other factors which in the Director's judgment are reasonable to take into account under the circumstances of a particular case. For example, in determining whether a domestic manufacturer is able to produce a custom-made instrument, the Director may take into account the production experience of the domestic manufacturer including (i) the types, complexity and capabilities of instruments the manufacturer has produced, (ii) the extent of the technological gap between the instrument to which the application relates and the manufacturer's customary products, (iii) the manufacturer's technical skills, (iv) the degree of saturation of the manufacturer's production capability, and (v) the time required by the domestic manufacturer to produce the instrument to the purchaser's specification. Whether or not the domestic manufacturer has field tested or demonstrated the instrument will not, in itself, enter into the decision regarding the manufacturer's ability to manufacture an instrument. Similarly, in determining whether a domestic manufacturer is willing to produce an instrument, the Director may take into account the nature of the bid process, the manufacturer's policy toward manufacture of the product(s) in question, the minimum size of the manufacturer's production runs, whether the manufacturer has bid similar instruments in the past, etc. Also, if a domestic manufacturer was formally requested to bid an instrument, without reference to cost limitations and within a leadtime considered reasonable for the category of instrument involved, and the domestic manufacturer failed formally to respond to the request, for the purposes of this section the domestic manufacturer would not be considered willing to have supplied the instrument.

(3) *Burden of proof.* The burden of proof shall be on the applicant to demonstrate that no instrument of equivalent scientific value for the purposes for which the foreign instrument is to be used is being manufactured in the United States. Evidence of applicant favoritism towards the foreign manufacturer (advantages not extended to domestic firms, such as additional lead time, know-how, methods, data on pertinent specifications or intended uses, results of research or development, tools, jigs, fixtures, parts, materials or test equipment) may be, at the Director's discretion, grounds for rejecting the application.

(4) *Excessive delivery time.* Duty-free entry of the instrument shall be considered justified without regard to whether there is being manufactured in the United States an instrument of equivalent scientific value for the intended purposes if excessive delivery time for the domestic instrument would seriously impair the accomplishment of the applicant's intended purposes. For purposes of this section, (i) except when objective and convincing evidence is presented that, at the time of order, the actual delivery time

would significantly exceed quoted delivery time, no claim of excessive delivery time may be made unless the applicant has afforded the domestic manufacturer an opportunity to quote and the delivery time for the domestic instrument exceeds that for the foreign instrument; and (ii) failure by the domestic manufacturer to quote a specific delivery time shall be considered a non-responsive bid (see §301.5(d)(2)). In determining whether the difference in delivery times cited by the applicant justifies duty-free entry on the basis of excessive delivery time, the Director shall take into account (A) the normal commercial practice applicable to the production of the general category of instrument involved; (B) the efforts made by the applicant to secure delivery of the instruments (both foreign and domestic) in the shortest possible time; and (C) such other factors as the Director finds relevant under the circumstances of a particular case.

(e) *Denial without prejudice to resubmission (DWOP).* The Director may, at any stage in the processing of an application by the Department of Commerce, DWOP an application if the application contains any deficiency which, in the Director's judgment, prevents a determination on its merits. The Director shall state the deficiences of the application in a letter to the applicant in making the provisional denial.

(1) The applicant has 60 days from the date of the DWOP to correct the cited deficiencies in the application unless a request for an extension of time for submission of the supplemental information has been received by the Director prior to the expiration of the 60-day period and is approved.

(2) The written request (letter or telegram) for an extension should indicate the reasons for the request and the amount of additional time needed. If granted, extensions of time will generally be limited to 30 days.

(3) Resubmissions must reference the application number of the earlier application. The resubmission shall be made by letter and filed in quadruplicate with the Director. The record of a resubmitted application shall include the original submission on file with the Department. Any new material or information contained in a resubmission, which should address the specific deficiencies cited in the DWOP letter, should be clearly labeled and referenced to the applicable question(s) on the application form. The resubmission should be signed and dated by the individual in the applicant institution who signed the original application or, in his/her absence, the individual in the applicant institution under whose direction and control the foreign instrument will be used and who is familiar with the intended uses of the instrument. The resubmission must be for the instrument covered by the original application unless the DWOP letter specifies to the contrary. The resubmission shall be subject to the certification contained in question 11 on the original application.

(4) If the applicant fails to resubmit within the applicable time period, the prior DWOP shall, irrespective of the merits of the case, result in a denial of the application.

(5) The Director shall use the postmark date of the fully completed resubmission in determining whether the resubmission was made within the allowable time period. Certified or registered mail, or some other means which can unequivocally establish the date of mailing, is recommended.

(6) The applicant may, at any time prior to the end of the resubmission period, notify the Director in writing that it does not intend to resubmit the application. Upon such notification, the application will be deemed to have been withdrawn. (See §301.5(g).)

(7) Information provided in a resubmission that, in the judgment of the Director, contradicts or conflicts with information provided in a prior submission, or is not a reasonable extension of the information contained in the prior submission, shall not be considered in making the decision on an application that has been resubmitted. Accordingly, an applicant may elect to reinforce an orginal submission by elaborating in the resubmission on the description of the purposes contained in a prior submission and may supply additional examples, documentation and/or other clarifying detail, but the applicant shall not introduce new purposes

or other material changes in the nature of the original application. The resubmission should address the specific deficiencies cited in the DWOP. The Director may draw appropriate inferences from the failure of an applicant to attempt to provide the information requested in the DWOP.

(8) In the event an applicant fails to address the noted deficiencies in the response to the DWOP, the Director may deny the application.

(9) Upon receipt of a responsive resubmission the Director shall publish a notice in the FEDERAL REGISTER citing the number of the earlier application, the name and address of the applicant institution, the instrument(s) involved, and any other information the Director deems relevant. The notice will also include the FEDERAL REGISTER citation for the original notice of application. Procedures applicable to comments on the processing of original applications shall thereafter apply.

(f) *Decisions on applications.* The Director shall prepare a written decision granting or denying each application. However, when he deems appropriate, the Director may issue a consolidated decision on two or more applications. The Director shall promptly forward a copy of the decision to each applicant institution and to the FEDERAL REGISTER for publication.

(g) *Withdrawal of applications.* The Director shall discontinue processing an application withdrawn by the applicant and shall publish notice of such withdrawal in the FEDERAL REGISTER. If at any time while its application is pending before the Director, either during the intital application or resubmission stage, an applicant cancels an order for the instrument to which the application relates or ceases to have a firm intention to order such instrument or apparatus, the institution shall promptly notify the Director. Such notification shall constitute a withdrawal. Withdrawals shall be considered as having been finally denied for purposes of § 301.7(c) below.

(h) Nothing in this subsection shall be construed as limiting the Director's discretion at any stage of processing to insert into the record and consider in making his decision any information in the public domain which he deems relevant.

[47 FR 32517, July 28, 1982; 47 FR 34368, Aug. 9, 1982, as amended at 50 FR 11501, Mar. 22, 1985]

§ 301.6 Appeals.

(a) An appeal from any decision made pursuant to § 301.5(f) may be taken, in accordance with headnote 6(e) to part 4 of Schedule 8, only to the U.S. Court of Customs and Patent Appeals and only on questions of law, within 20 days after publication of the decision in the FEDERAL REGISTER. If at any time while its application is under consideration by the Court of Customs and Patent Appeals on an appeal from a finding by the Director an institution cancels an order for the instrument to which the application relates or ceases to have a firm intention to order such instrument, the institution shall promptly notify the court.

(b) An appeal may be taken by: (1) The institution which makes the application;

(2) A person who, in the proceeding which led to the decision, timely represented to the Secretary of Commerce in writing that he/she manufactures in the United States an instrument of equivalent scientific value for the purposes for which the instrument to which the application relates is intended to be used;

(3) The importer of the instrument, if the instrument to which the application relates has been entered at the time the appeal is taken; or

(4) An agent of any of the foregoing.

(c) Questions regarding appeal procedures should be addressed directly to the U.S. Court of Customs and Patent Appeals, Clerks' Office, Washington, DC 20439.

§ 301.7 Final disposition of an application.

(a) Disposition of an application shall be final when 20 days have elapsed after publication of the Director's final decision in the FEDERAL REGISTER (see § 301.6(a)) and no appeal has been taken pursuant to § 301.6 of these regulations, of if such appeal has been taken, when final judgment is made and entered by the Court.